UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK
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IN RE CIPROFLOXACIN HYDROCHLORIDE ANTITRUST LITIGATION

MEMORANDUM AND ORDER

1:00-MDL-1383 (DGT)

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TRAGER, J.

This action involves agreements between the brand-name manufacturer of the widely used antibiotic ciprofloxacin hydrochloride ("Cipro") and potential generic manufacturers of Cipro. The brand-name manufacturer, Bayer AG, a German company, and its American subsidiary, Bayer Corporation (collectively, "Bayer") and the generics, Barr Laboratories, Inc. ("Barr"); The Rugby Group, Inc. ("Rugby"); Hoechst Marion Roussel, Inc. ("HMR"); and Watson Pharmaceuticals, Inc. ("Watson") (collectively, "generic defendants")[1] entered into agreements that Direct Purchaser Plaintiffs ("direct plaintiffs") and Indirect Purchaser Class Plaintiffs ("indirect plaintiffs")

[1] Barr and Rugby are in the business of, inter alia, manufacturing and marketing generic drugs. Rugby was the U.S. generic drug subsidiary of HMR until February 1998, when Rugby was acquired by Watson, a company that produces and distributes generic and brand-name drugs. Watson is not a signatory to any of the allegedly unlawful agreements.

allege prevented competition in the market for Cipro in violation of federal and state antitrust laws.[2] Plaintiffs previously filed motions for partial summary judgment seeking a determination that these agreements were per se unlawful under Section 1 of the Sherman Act, 15 U.S.C. § 1 (and various state antitrust and consumer protection laws), which were denied. Subsequently, indirect plaintiffs amended their complaint to add a new count, Count V, alleging Walker Process-type[3] and sham litigation antitrust violations under state law.

Bayer and generic defendants have now each filed motions for summary judgment asserting that these agreements do not violate Section 1 of the Sherman Act because they had no anti-competitive effects beyond the scope of Bayer's patent on ciprofloxacin, while direct plaintiffs have filed a motion for partial summary judgment arguing that the agreements meet the "anti-competitive

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[2] The generic defendants, together with Bayer, will be referred to as the "defendants," while direct plaintiffs and indirect plaintiffs will be referred to as "plaintiffs."

[3] In Walker Process Equipment, Inc. v. Food Machinery & Chem. Corp., 382 U.S. 172, 177, 86 S.Ct. 347, 15 L.Ed.2d 247 (1965), the Supreme Court first recognized an antitrust cause of action based on assertion of a patent known to have been obtained by fraud on the United States Patent and Trademark Office ("PTO"), provided that the other elements of a Sherman Act claim are present. Such claims are commonly referred to as Walker Process claims. Because indirect plaintiffs are asserting their claims under state law and because they have pointed to no state law explicitly recognizing an antitrust claim for assertion of a patent obtained by fraud, their claim is referred to as a Walker Process-type claim.

conduct" requirement of Section 1 of the Sherman Act and the "antitrust injury" requirement of the Section 4 of the Clayton Act. Bayer has also filed two motions relating to Count V of indirect plaintiffs' second amended complaint ("Count V"). The first, a motion to dismiss Count V, is made on the grounds that indirect plaintiffs' state law Walker Process-type claim is preempted by federal patent law and is barred by the statute of limitations. The second, filed in the event Count V is not dismissed, is a motion for summary judgment on Count V on the grounds that indirect plaintiffs have failed to demonstrate that any misrepresentations or omissions made by Bayer in prosecuting its patent were so highly material that the patent would not have issued but for the alleged deceptions and that plaintiffs' sham litigation claim fails as a matter of law. Finally, HMR and Rugby have filed a motion for summary judgment that indirect plaintiffs' claims against them are barred by the doctrine of Illinois Brick[4] and that any rights assigned to indirect plaintiffs do not include claims against HMR.

[4] Under Illinois Brick Co. v. Illinois, 431 U.S. 720, 97 S.Ct. 2061, 52 L.Ed.2d 707 (1977), indirect purchasers are barred from recovering damages for monopolistic overcharges under federal antitrust law.

Background

The statutory and regulatory background, as well as the circumstances of this case, were fully described in the court's initial opinion, In re Ciprofloxacin Hydrochloride Antitrust Litig., 166 F. Supp. 2d 740 (E.D.N.Y. 2001) ("Cipro I") (granting certain plaintiffs' motions to remand to state court). The developments in the case were further discussed and analyzed in a second opinion, In re Ciprofloxacin Hydrochloride Antitrust Litig., 261 F. Supp. 2d 188 (E.D.N.Y. 2003) ("Cipro II") (granting in part and denying in part defendants' motions to dismiss, and denying plaintiffs' motion for partial summary judgment asserting that the agreements constituted per se violations of the antitrust laws). Familiarity with those decisions is presumed, and what follows is a summary of only those facts necessary for the resolution of the pending motions.

Bayer is the assignee of U.S. Patent No. 4,670,444 ("the '444 Patent"), a compound patent which claims the chemical entity that is the active ingredient in Cipro – ciprofloxacin hydrochloride – and all its generic equivalents. See Cipro II, 261 F. Supp. 2d at 249 ("A patent on a compound that is the only active ingredient in a drug covers all generic versions of that drug . . . . regardless of how formulated, processed or delivered . . . ."). The '444 Patent issued on June 2, 1987 from patent application Ser. No. 614,923 ("the '923 application"), which was

filed on May 29, 1984. The '923 application was filed as a continuation-in-part[5] of Ser. No. 292,560 ("the '560 application"), which was filed on August 13, 1981, and Ser. No. 436,112 ("the '112 application"), which was filed on October 22, 1982. See App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V App."), Ex. 1.

In October 1987, Bayer's predecessor, Miles, Inc., obtained FDA approval to market Cipro in the United States. Cipro II, 261 F. Supp. 2d at 194. From 1987 until 2004, Bayer was the only producer of Cipro in the United States. Id. On October 22, 1991, Barr filed Abbreviated New Drug Application ("ANDA") 74-124 for permission to market a generic version of Cipro, and included a Paragraph IV certification, seeking permission to market its generic drug before expiration of the '444 Patent on the grounds that the patent was invalid and unenforceable. Id. Because the '444 Patent claims the active ingredient in Cipro and because Barr was required in its ANDA to certify that its generic version of Cipro was bioequivalent to Bayer's Cipro, there is no dispute that Barr's product would have infringed Bayer's patent. Cipro

[5] A continuation-in-part application is an application that claims priority to and includes the subject matter of at least part of an earlier-filed application.

II, at 249; see also App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Pls. Claims Under the Sherman Act and Corr. State Law Claims ("Bayer Sherman Act App."), Tab 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)).

Pursuant to the Hatch-Waxman Amendments to the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355, on December 6, 1991, Barr notified Bayer of its ANDA IV filing, and on January 16, 1992, Bayer sued Barr for patent infringement in the Southern District of New York, where the case was assigned to Judge Whitman Knapp. Cipro II, 261 F. Supp. 2d at 194. In January 1996, Bayer and Barr filed cross-motions for partial summary judgment, which Judge Knapp denied in an order and opinion dated June 5, 1996. Id. at 195. In March 1996, while these cross-motions were sub judice, Barr agreed to share equally any profits from the eventual marketing and/or distribution of Cipro with Rugby, which was then a subsidiary of HMR, and, in return, Rugby agreed to finance a portion of the costs and expenses of the patent litigation against Bayer. Id.

On January 8, 1997, just weeks before trial was scheduled to begin, Bayer and Barr reached a settlement of the patent litigation, with Bayer entering into three separate agreements with Barr, HMR and Rugby, and Bernard Sherman and Apotex, Inc. (collectively, the "Settlement Agreements") and a supply

agreement with Barr and HMR (the "Supply Agreement") (collectively with the Settlement Agreements, the "Agreements"), the terms of which give rise to the plaintiffs' claims of Sherman Act violations. Id. at 195-96. Under the Barr Settlement Agreement, Bayer paid Barr $49.1 million and, in return, required Barr to amend its ANDA from a Paragraph IV certification to a Paragraph III certification, which would permit it to market a generic form of Cipro only upon the expiration of the '444 Patent. Id. at 196. However, the Barr Settlement Agreement preserved the option for Barr to re-amend to a Paragraph IV certification (for the purpose of reclaiming the 180-day exclusivity period that is awarded to a first-filer of an ANDA IV) in the event the '444 Patent were subsequently declared invalid or unenforceable by a court of competent jurisdiction. Bayer Sherman Act App., Ex. 16 ¶ 5(a); see Cipro II, 261 F. Supp. 2d at 243-47.

Under the terms of the Supply Agreement, Barr and HMR agreed not to manufacture or have manufactured a generic form of Cipro in the United States. Cipro II, 261 F. Supp. 2d at 196. The Supply Agreement further provides that Bayer will either supply Bayer-manufactured Cipro to Barr, HMR and Rugby for distribution in the United States, or make quarterly payments to Barr from January 1998 through December 2003, at which time the '444 Patent was due to expire. Id. Bayer opted to make the payments, which,

by December 2003, when added to the initial $49.1 million payment, totaled approximately $398 million. Id.

Bayer and Barr also entered into a Consent Judgment, terminating the litigation, in which Barr affirmed the validity and enforceability of the '444 Patent and admitted infringement. Id. at 196; Bayer Sherman Act App., Ex. 18. The Consent Judgment was signed by Judge Knapp, but made no mention of any payments from Bayer to Barr. Id.

Six months after settling with Barr, in July 1997, Bayer submitted the '444 Patent to the Patent and Trademark Office ("PTO") for reexamination. During the reexamination, Bayer amended certain of the claims of the '444 Patent and cancelled others, after which the PTO reaffirmed the patent's validity, including the validity of claim 12, which was not substantively amended and which all parties agree covers ciprofloxacin hydrochloride. Id. at 197; Bayer's Reply Mem. in Supp. of Its Mot. for Partial Summ. J. on Count V of the Indirect Purchaser Class Pls.' Proposed Second Am. Consolidated Class Action Compl. ("Bayer's Count V Reply Mem.") at 19; Bayer Sherman Act App., Ex. 5; App. to Aff. of Paul J. Skiermont in Support of Bayer's Mot. for Partial Summ. J. on Count V of the Indir. Pls.' Proposed Second Am. Consol. Class Action Compl. ("Bayer Count V S.J. App."), Ex. 9. Thereafter, four other generic companies – Schein, Mylan, Carlsbad and Ranbaxy – each challenged the

reexamined '444 Patent by filing ANDA IVs for Cipro. Cipro II, 261 F. Supp. 2d at 197. Bayer defeated Schein and Mylan's validity challenges on summary judgment, and those decisions were upheld by the Court of Appeals for the Federal Circuit. Id. at 201. The Carlsbad case proceeded to a nine-day bench trial, after which the judge rejected Carlsbad's invalidity argument and upheld the validity of the '444 Patent. See Bayer Count V App., Exs. 15 and 16 (Bayer AG v. Carlsbad Tech., Inc., No. 01-cv-0867-B, slip op. at 5-13 (S.D. Cal. June 7, 2002 and Aug. 7, 2002)). Ranbaxy's challenge was dismissed as moot after Ranbaxy withdrew its Paragraph IV certification. Cipro II, 261 F. Supp. 2d at 197.

Discussion

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Sherman Act Motions for Summary Judgment

The Cipro II decision made clear that Barr's agreement with Bayer not to sell ciprofloxacin in exchange for the exclusion payments, also commonly known as reverse or exit payments,[6] did not constitute a per se violation of the Sherman Act because the

[6] In briefing these motions, the parties have sometimes referred to these payments as "reverse" payments. Adoption herein of the "exclusion payments" nomenclature is made for ease of reference, and in recognition that the payments, whatever they are called, are made in exchange for a competitor's exit or exclusion from the relevant market.

exclusionary effect of the Agreements was within the scope of the '444 Patent. Direct plaintiffs now move for summary judgment that the exclusion-payment scheme meets the "anti-competitive conduct" requirement of Section 1 of the Sherman Act under a rule of reason analysis, while both Bayer and generic defendants move for summary judgment that the Agreements had no anti-competitive effects that are actionable under the Sherman Act because they were within the scope of the '444 Patent. Resolution of this issue requires a close look at the intersection of patent and antitrust laws.

The rule of reason analysis involves a three-step process. First, the plaintiff must prove that "the challenged action has had an actual adverse effect on competition as a whole in the relevant market." K.M.B. Warehouse Distributors, Inc. v. Walker Mfg. Co., 61 F.3d 123, 127 (2d Cir. 1995) (emphasis in original) (quoting Capital Imaging Assocs. v. Mohawk Valley Med. Assocs., 996 F.2d 537, 543 (2d Cir.), cert. denied, 510 U.S. 947, 114 S.Ct. 388, 126 L.Ed.2d 337 (1993)). Next, "the burden shifts to the defendant to establish the 'pro-competitive redeeming virtues' of the action." Id. If the defendant succeeds, the burden shifts back to the plaintiff to "show that the same pro-competitive effect could be achieved through an alternative means

that is less restrictive of competition." Id.[7,8]

a. Relevant market

Taking these steps one at a time, the first question is whether plaintiffs have shown that the Agreements had an actual adverse effect on competition in the relevant market. Traditionally, the starting point of an antitrust inquiry is the definition of the relevant market. See, e.g., Geneva Pharma.

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[7] Summary judgment is appropriate only in those cases were there is no genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 106 S.Ct. 2548, 91 L.Ed.2d 265 (1986). Here, Bayer, generic defendants and direct plaintiffs have each filed motions for summary judgment on the issue of whether the Bayer/Barr settlement agreements had an anti-competitive effect. The burden of proving anti-competitive effects lies with the plaintiffs in the first instance, and, as discussed infra, plaintiffs have shown no anti-competitive effects beyond the scope of the '444 Patent. The analysis with respect to those anti-competitive effects that are within the scope of the '444 Patent (and which all parties agree were present) constitutes a pure discussion of law without regard to burdens of proof.

[8] A recent decision by the Eleventh Circuit questions the appropriateness of the per se versus rule of reason approach for claims of antitrust violations involving patents. See Schering-Plough v. Federal Trade Comm'n, __ F.3d __, __, 2005 WL 528439, at *7 (11th Cir. Mar. 8, 2005). The Eleventh Circuit's opinion can fairly be read as breaking the first step of a rule of reason analysis – assessing the actual adverse effects on competition – into three steps to determine whether there are any anti-competitive effects that exceed the scope of the patent. Regardless of whether the Eleventh Circuit intended to jettison the rule of reason analysis in the patent context or simply refine the analysis, the case at bar will be considered under this court's prior opinion adopting the rule of reason mode of analysis. See Cipro II, 261 F. Supp. 2d at 256-57. It would be inappropriate not to address the issue accordingly, not least because the parties have briefed the issue in light of that analysis. In any event, the same result would be reached under either analytical approach.

Tech. Corp. v. Barr Labs. Inc., 386 F.3d 485, 496 (2d Cir. 2004) ("Evaluating market power begins with defining the relevant market."). The purpose of this inquiry is to determine whether defendants possess market power, i.e., the ability to lessen or destroy competition, which, while not the sine qua non of a violation of Section 1 of the Sherman Act, is "a highly relevant factor in rule of reason analysis because market power bears a particularly strong relationship to a party's ability to injure competition." Capital Imaging, 996 F.2d at 546. The parties dispute whether the relevant market comprises only ciprofloxacin, as plaintiffs have asserted in their complaint, see Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 34, or includes other drugs in the same molecular family as ciprofloxacin (flouroquinolones), which Bayer contends compete with ciprofloxacin in the U.S. antibiotic market, see Bayer Defs.' Mem. of Law in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Bayer's Opp. Mem."), at 26-29.

Plaintiffs assert that it is unnecessary to show a relevant market in this case because there exists direct evidence of anti-competitive effects. Mem. in Support of Direct Purchaser Pls.' Mot. for Partial Summ. J. ("Dir. Pls.' Mem."), at 25. In general, to sidestep the traditional relevant market analysis, a plaintiff must show by direct evidence "an actual adverse effect on competition, such as reduced output." Geneva v. Barr, 386

F.3d at 509 ("If plaintiff can demonstrate an actual adverse effect on competition, such as reduced output, . . . there is no need to show market power in addition.") (citing FTC v. Indiana Fed'n of Dentists, 476 U.S. 447, 460-61, 106 S.Ct. 2009, 2019, 90 L.Ed.2d 445 (1986); K.M.B. Warehouse, 61 F.3d at 128-29). The reason for permitting this alternative showing is simply that the purpose of an inquiry into market power "is to determine whether an arrangement has the potential for genuine adverse effects on competition." FTC v. Indiana Fed'n of Dentists, 476 U.S. at 460, 106 S.Ct. at 2019. In effect, market power is "but a 'surrogate for detrimental effects.'" Id., 476 U.S. at 461, 106 S.Ct. at 2019 (quoting 7 P. Areeda, Antitrust Law ¶ 1511, p. 429 (1986)).

For their direct evidence showing, direct plaintiffs point to government and academic studies concluding that purchasers derive substantial savings from the availability of generic drugs; internal analyses by the brand name and generic manufacturers themselves forecasting significant price reductions once generic drugs become available; and sales data showing the actual effects of competition once generic Cipro was introduced into the market. Dir. Pls.' Mem. at 25-31. In particular, direct plaintiffs rely on a 1998 study by the Congressional Budget Office comparing brand-name and generic prices for twenty-one different drugs that faced generic competition between 1991 and 1993, which found that the average retail price of a

prescription for a generic drug in 1994 was less than half the average brand-name drug price. App. in Support of Decl. of Monica L. Rebuck for Dir. Pls.' Mot. for Partial Summ. J. (Dir. Pls.' Summ. J. App.), Tab 5 (Congressional Budget Office, How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry, at 28-31 (July 1998) ("CBO Study")). Another study cited by direct plaintiffs found that by 2000, the average brand-name prescription cost 340 percent more than its generic equivalent ($65.29 versus $19.33). Dir. Pls.' Summ. J. App., Tab 20 (Kirkling et al., Economics and Structure of the Generic Pharmaceutical Industry, 41 J. Amer. Pharm. Assoc. 578, 579 (2001)).

These studies notwithstanding, the significant price differences actually suggest a finding contrary to the one implied by plaintiffs. Namely, brand-name pharmaceuticals and their generic counterparts might not always compete in the same markets at all because, based on the higher prices of the brand-name drugs, there is less cross-elasticity of demand than one might expect. (If there were, the prices for brand-name drug prices should fall and be closer to that of generics). Indeed, the CBO Study cited by plaintiffs indicates that prices for brand-name drugs continue to rise faster than inflation even after generic competition begins. CBO Study at 30-31. The Second Circuit recently relied on similar price differential data

to reach a particularly narrow market definition in Geneva v. Barr, 386 F.3d at 496-500. In that case, the court, relying on the factors set forth in Brown Shoe Co. v. United States, 370 U.S. 294, 325, 82 S.Ct. 1502, 1524, 8 L.Ed. 1264 (1956), defined the market as limited to generic warfarin sodium. Id.; see also Asahi Glass Co., Ltd. v. Pentech Pharma., Inc., 289 F. Supp. 2d 986, 995-96 (N.D. Ill. 2003) (Posner, J., sitting by designation) (noting that paroxetine, the active ingredient in Paxil, competes with molecules that are the basis for other antidepressant drugs such as Prozac and Zoloft, but reserving the possibility that paroxetine might still warrant treatment as a separate market).

Despite the fact that brand-name pharmaceuticals are apparently able to maintain significantly higher prices even after generic entry, the parties' internal analyses prepared at the time the Agreements were entered into confirm that both Bayer and Barr expected Bayer to lose significant sales once generic competition began, with Bayer estimating losses of between $510 million and $826 million in Cipro sales during the first two years of generic competition, depending on the number of generic manufacturers entering the market. Dir. Pls.' Summ. J. App., Tab 47A, at BCP4630078. Another contemporaneous internal Bayer document estimated Bayer's losses due to a potential adverse judgment in the '444 Patent litigation at $1.679 billion net present value. Dir. Pls.' Summ. J. App., Tab 47D at BCP-P-

0001572-004(2). Barr, similarly, projected that it and other generic manufacturers would capture a large percentage of the market for ciprofloxacin within the first two years of generic competition, and would enter the market at a 30 percent discount off Bayer's price. Dir. Pls.' Summ. J. App., Tab 36A at BLI-003560.

Finally, direct plaintiffs point to post-generic entry data showing that Barr in fact did capture more than 50 percent of Bayer's Cipro sales soon after entering the market, and that it initially priced its generic ciprofloxacin at only 8 percent below Bayer's Cipro product. Dir. Pls.' Summ. J. App., Tab 35 (Expert Report of Jeffrey J. Leitzinger, Ph.D., at 38 n.93). Direct plaintiffs also note that the Amended and Restated Supply Agreement between Bayer and Barr, dated August 28, 2003, which provides for Bayer to continue supplying ciprofloxacin to Barr for resale after expiration of the pediatric marketing exclusivity extension that Bayer obtained pursuant to 21 U.S.C. § 355a, sets drastically reduced prices for Cipro after the commencement of open generic competition. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. For example, a 100-pill bottle of oral, 500-mg ciprofloxacin that cost Barr $321.96 before the beginning of open generic competition would cost only $14.30 after the expiration of Bayer's pediatric exclusivity, a 95 percent difference in price. Id. Bayer has admitted that the

purpose of the price drop was to allow Barr to compete with additional generic manufacturers who would then be entering the market. Dir. Pls.' Summ. J. App., Tab 80 at 112.

Bayer discounts the import of these facts, insisting instead that Cipro competes in the larger market of flouroquinolones, which includes other drugs such as Levaquin, Floxin and Noroxin, within which Cipro has been losing market share, from 75 percent in 1996 to 43 percent in 2001. Bayer's Opp. Mem. at 28-29. Bayer maintains that a properly defined market must include all quinolone antibiotics and that defendants did not possess enough market power to control prices or exclude competition within that larger market. Id. at 29.

Although evidence that Bayer charged high prices for Cipro "may of course be indicative of monopoly power," it is not necessarily conclusive in the absence of any analysis of Bayer's costs. See, e.g., Geneva v. Barr, 386 F.3d at 500. Plaintiffs have provided neither evidence of Bayer's costs nor any direct evidence that defendants restricted output. However, the pricing strategy encompassed in the Amended and Restated Supply Agreement compels an inference that Bayer was reaping an abnormally high price-cost margin, given the 95 percent price drop that was to occur almost a full year in the future for an identical quantity of an identical strength of the identical drug. Dir. Pls.' Summ. J. App., Tab 43A at BCP4660023. Given Bayer's obvious ability to

control prices, and its admission that it did not anticipate a commensurate drop in its own production costs for Cipro,[9] it is reasonable to accept plaintiffs' contention and conclude both that the relevant market is for ciprofloxacin and that Bayer had market power within that market.

b. Adverse effect on competition

The ultimate question – and this is the crux of the matter – is not whether Bayer and Barr had the power to adversely affect competition for ciprofloxacin as a whole, but whether any adverse effects on competition stemming from the Agreements were outside the exclusionary zone of the '444 Patent. It goes without saying that patents have adverse effects on competition. See Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 816, 65 S.Ct. 993, 998, 89 L.Ed 1381 (1945) (A patent "is an exception to the general rule against monopolies and to the right to access to a free and open market."); Schering-Plough, __ F.3d at __, 2005 WL 528439, at *7 ("By their nature, patents create an environment of exclusion, and consequently, cripple competition.

[9] Bayer admitted at oral argument that its estimated costs of production did not change after the exclusivity period, but contends that its marketing costs were projected to drop sharply after generic entry. It is understandable that Bayer would choose to spend less to promote Cipro at a time when its marketing efforts would not redound exclusively to its own benefit, but a drop in such discretionary spending only further illustrates the degree to which Bayer controlled its own profit margin.

The anticompetitive effect is already present."). However, any adverse effects within the scope of a patent cannot be redressed by antitrust law. See United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127 (D.C. Cir. 1981) ("[T]he conduct at issue is illegal if it threatens competition in areas other than those protected by the patent and is otherwise legal."); see also United States v. General Electric Co., 272 U.S. 476, 485, 47 S.Ct. 192, 195, 71 L.Ed. 362 (1926); E. Bement & Sons v. National Harrow Co., 186 U.S. 70, 91, 22 S.Ct. 747, 755, 46 L.Ed. 1058 (1902). The '444 Patent gave Bayer the right to exclude competition entirely for ciprofloxacin for the term of the patent, and any conduct within the scope of the patent is exempt from antitrust scrutiny. See Cipro II, 261 F. Supp. 2d at 248 ("[A] patent holder does not run afoul of the Sherman Act unless the patent holder acts beyond the confines of the patent monopoly."). Defendants argue that a determination that the Agreements do not restrict competition beyond the scope of the claims of the '444 Patent ends the inquiry as to anti-competitive effects. Plaintiffs, on the other hand, argue that the exclusionary power of the patent for purposes of the anti-competitive effects analysis should be tempered by its potential invalidity.

i. The validity inquiry

While there have been to date only a handful of cases

discussing the legality of patent settlement exclusion payments, some courts and commentators have dealt with the questions of whether and to what extent the validity of the patent should be a factor in appraising the legality of an exclusion payment, and what sort of inquiry into validity an antitrust court should make. The Second Circuit has not yet addressed these issues, but two federal circuits, two district courts (including one on which Judge Posner sat by designation) and the Federal Trade Commission ("FTC") have considered them. Although those courts have come to different conclusions regarding the legality of exclusion payments at issue in those cases, they have generally agreed that an antitrust court need not make an independent assessment of the underlying patent's validity.

The Eleventh Circuit's approach in Valley Drug

The Eleventh Circuit in Valley Drug Co. v. Geneva Pharma., Inc., 344 F.3d 1294 (11th Cir. 2003), held that to the extent the effects of the subject settlement agreements are within the scope of the exclusionary potential of the patent, such effects are not subject to per se (or rule of reason) antitrust condemnation, even where the patent is later held invalid. Valley Drug, 344 F.3d at 1311. The two agreements at issue in that case were between Abbott, manufacturer of the pioneer drug Hytrin, and two of its generic competitors – Geneva and Zenith. Id. at 1296. Abbott held multiple patents on Hytrin, a drug containing

terazosin hydrochloride, which is used to treat hypertension and enlarged prostate, and Geneva filed several ANDA IVs on Hytrin over a period of years. Id. at 1298. Zenith, meanwhile, had also filed an ANDA IV on Hytrin, which was pending when two additional patents relating to the active ingredient in Hytrin were issued to Abbott. Id. Abbott listed the new patent information with the FDA, which then required Zenith to make a certification with respect to the newly-issued patents. Id. Rather than comply, Zenith filed suit against Abbott to force Abbott to delist the new patents, alleging that Abbott listed them with the knowledge that they were not applicable to Hytrin. Id.

On March 31, 1998, Abbott and Zenith entered an agreement settling their delisting and infringement dispute, under which Zenith agreed not to sell or distribute any generic terazosin hydrochloride product until a third party entered the market or until one of Abbott's patents expired, in exchange for payments by Abbott of $6 million every three months. Id. at 1300. The next day, Abbott entered a similar agreement with Geneva whereby Geneva agreed not to sell or distribute any generic terazosin hydrochloride product until one of Abbott's patents expired, a third party entered the market or Geneva obtained a final court judgment from which no further appeal could be taken that its terazosin products did not infringe one of Abbott's patents or

that the patent was invalid. Id. In exchange, Abbott agreed to pay Geneva $4.5 million per month. Id. Geneva subsequently prevailed in the patent infringement suit Abbott had filed against it, obtaining a judgment on September 1, 1998 that the patent at issue in that case was invalid. Id. at 1301.

The district court concluded that Abbott's agreements with Zenith and Geneva were per se violations of Section 1 of the Sherman Act, holding that the exclusionary effect of the agreements constituted an allocation of the market between horizontal competitors. Id. at 1304. The Eleventh Circuit reversed, however, rejecting the argument "that the agreements by Geneva and Zenith not to produce infringing products are subject to per se condemnation and treble-damages liability merely because the '207 patent was subsequently declared invalid." Id. at 1306. The court ruled that "the mere subsequent invalidity of the patent does not render the patent irrelevant to the appropriate antitrust analysis." Id. at 1306-07. The court invoked the rationale of Justice Harlan's concurrence in Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 179-80, 86 S.Ct. 347, 351-52, 15 L.Ed.2d 247 (1965): "[T]o hold, as we do not, that private antitrust suits might also reach monopolies practiced under patents that for one reason or another may turn out to be voidable under one or more of the numerous technicalities attending the issuance of a patent, might well

chill the disclosure of inventions through the obtaining of a patent because of fear of the vexations or punitive consequences of treble-damage suits." Id. at 1307. The court accordingly reserved any post hoc validity analysis for those cases in which the patent was procured by fraud or known by the patentee to be invalid. Id. at 1307.

The court concluded that "[p]atent litigation is too complex and the results too uncertain for parties to accurately forecast whether enforcing the exclusionary right through settlement will expose them to treble damages if the patent immunity were destroyed by the mere invalidity of the patent." Id. at 1308. The court held open the possibility that the size of the payment to refrain from competing could be evidence of a lack of faith in the validity of the patent or evidence that the patent was obtained by fraud but, citing this court's decision in Cipro II, noted that the asymmetries of risk inherent in a Hatch-Waxman patent litigation and the high profits at stake could induce even a confident patentee to pay a substantial sum in settlement. Id. at 1309-10.

The Valley Drug court thus took the position that an antitrust court need not consider the potential invalidity of the patent in an exclusion-payment settlement, except in those extreme cases involving fraud on the Patent Office or assertion of a patent known to be invalid, i.e., in circumstances giving

rise to an allegation of Walker Process fraud or sham litigation. However, the court went on to direct the district court on remand to evaluate the defendants' claim that the exclusionary effects of the patent and the agreements were coextensive because certain provisions of the agreements were analogous to a consensual preliminary injunction and stay of judgment pending appeal. Id. at 1312. The court instructed that this evaluation should include a comparison between "the provisions of the agreement and the protections afforded by the preliminary injunction and stay mechanisms," and, furthermore, that the "likelihood of Abbott's obtaining such protections" should be considered. Id.

On remand, the district court interpreted the Eleventh Circuit's instructions as requiring an analysis of the likelihood that Abbott would have won a preliminary injunction at the time the agreements were executed, which it construed as requiring an analysis of whether Abbott would have been able to show that its patent was likely valid, rather than an analysis simply of whether the patent claims covered Abbott's product. In re Terazosin Hydrochloride Antitrust Litig., 352 F. Supp. 2d 1279, 1295 (S.D. Fl. 2005). The district court proceeded to determine the likely validity of the patent at the time the agreements were entered, employing the standards applicable to a preliminary injunction analysis. Id. at 1303-07. The district court ultimately concluded that Abbott would likely not have been able

to show that its patent was likely valid at the preliminary injunction stage of its suit against Geneva and, therefore, held that the Geneva agreement went beyond the exclusionary zone of the patent and was a per se violation of the Sherman Act.

It is not certain that the district court correctly interpreted the Eleventh Circuit's opinion, and, indeed, the Eleventh Circuit seems to have expressed some doubt on that point in an unrelated opinion. See Schering-Plough, __ F.3d at __, 2005 WL 528439, at *7 n.14 ("On remand, the district court in Valley Drug still applied a per se analysis. . . ."). In any event, the implication of the district court's reasoning conflicts with the proposition already rejected in Cipro II - that the legality of the Agreements is contingent on Barr's chances of having won at trial. See Cipro II, 261 F. Supp. 2d at 202 ("[P]laintiffs cannot avoid dismissal based on a claim of injury-in-fact that relies on the hope that Barr would have prevailed in its suit against Bayer.").

The Sixth Circuit's approach in Cardizem

The Sixth Circuit, in In re Cardizem CD Antitrust Litig., 332 F.3d 896 (6th Cir. 2003), also eschewed an analysis of the patent's validity in analyzing the anti-competitive effects of an exclusion-payment patent settlement agreement, although that court, unlike this one, concluded that such a settlement was a per se violation of the Sherman Act without considering the scope

of the underlying patent right. The agreement at issue in that case, however, contained provisions that clearly exceeded any competitive restrictions accruing to the defendants under patent law, particularly because the settling generic manufacturer, Andrx, did not relinquish its claim to 180 days of generic marketing exclusivity under the Hatch-Waxman Act. That is, a term of the agreement required that Andrx maintain its status as first-filer of an ANDA IV even after entering the agreement with the brand-name manufacturer. In re Cardizem, 332 F.3d at 902. Andrx's refusal to amend its ANDA to give up the exclusivity claim resulted in a market bottleneck since no other generic manufacturer could come to market until at least 180 days after Andrx began marketing the drug, a trigger that was postponed indefinitely by the settlement. Id. at 907. Thus, the brand-name manufacturer used the agreement to effectively bar third parties from mounting challenges to its patent – a power clearly not within the exclusionary power of a patent. Therefore, although the Sixth Circuit arrived at a different conclusion regarding per se liability, its approach was consistent with the position taken by this court in Cipro II – namely, that a patent holder cannot exploit the Hatch-Waxman provisions to create a bottleneck that indefinitely excludes subsequent generic challengers from the market. It is also clear that the Sixth Circuit did not engage in an after-the-fact analysis of the

patent's likely validity in reaching its determination.

Judge Posner's approach in Asahi Glass

Judge Posner, sitting by designation for the Northern District of Illinois, adopted similar reasoning to that of the Eleventh Circuit in Valley Drug in analyzing the merits of an antitrust action brought by a supplier to a generic pharmaceutical company that was shut out of the market for paroxetine hydrochloride (sold as the antidepressent Paxil) by a settlement agreement between the generic and the brand-name manufacturer. Asahi Glass, 289 F. Supp. 2d at 992-93. The agreement settled a Hatch-Waxman patent litigation and stipulated that the brand-name manufacturer would provide the finished drug product free of charge to the generic company, which would then sell it as an unbranded version of Paxil and pay a sizeable royalty to the brand-name manufacturer. The plaintiff, which had previously anticipated selling the active ingredient for the drug to the generic manufacturer, found itself without a customer, since the generic manufacturer had no incentive to pay for that which it was already getting for free from the brand-name drug maker. The plaintiff sued both parties to the agreement, alleging that the agreement violated Section 1 of the Sherman Act. Judge Posner dismissed the complaint on the ground that the agreement was a legitimate settlement of a patent infringement suit. Id. at 991.

Commenting on the hesitation of an antitrust court to delve into the merits of a predicate patent suit and its potential effect on a settlement agreement, Judge Posner noted:

> [T]he private thoughts of a patentee, or of the alleged infringer who settles with him, about whether the patent is valid or whether it has been infringed is not the issue in an antitrust case. A firm that has received a patent from the patent office (and not by fraud . . .), and thus enjoys the presumption of validity that attaches to an issued patent, 35 U.S.C. § 282, is entitled to defend the patent's validity in court, to sue alleged infringers, and to settle with them, whatever its private doubts, unless a neutral observer would reasonably think either that the patent was almost certain to be declared invalid, or the defendants were almost certain to be found not to have infringed it, if the suit went to judgment.

Id. at 992-93. Although Asahi Glass did not involve an exclusion-payment settlement, Judge Posner employed a similar approach to that of the Eleventh Circuit in Valley Drug in declining to independently assess the likely validity of the patent unless it was almost certainly invalid or obtained by fraud.[10, 11]

The district court's approach in Tamoxifen

This district has also previously adjudicated the legality

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[10] Neither the Eleventh Circuit nor Judge Posner furnished any examples of or provide further guidance regarding patents that were so blatantly invalid.

[11] It happens that Judge Posner did in fact decide the validity of the patent in a related patent infringement case that was decided prior to Asahi Glass. See Asahi Glass, 289 F. Supp. 2d at 992. In that case he found the patent to be valid. Id.

of a settlement of a patent litigation in which the validity of the patent was less than certain, without engaging in a post hoc analysis of the patent's validity. See In re Tamoxifen Citrate Antitrust Litig., 277 F. Supp. 2d 121 (E.D.N.Y. 2003) (Glasser, J.). In that case, the brand-name manufacturer, Zeneca, settled with the first generic challenger – coincidentally, Barr – after Barr had obtained a district court judgment, at that time on appeal, that the patent was invalid and unenforceable. Id. at 125. Under the settlement, Zeneca paid Barr $21 million and licensed Barr to sell tamoxifen manufactured by Zeneca for a royalty in exchange for Barr's withdrawal of its challenge to the validity to the patent and agreement not to market its generic version of tamoxifen until the patent expired. Id. Barr and Zeneca jointly moved the appeals court to dismiss the appeal as moot in light of the settlement and to vacate the judgment below, which motions were granted. Id. Three additional generic manufacturers subsequently challenged Zeneca's patent for tamoxifen, and the patent was upheld in each instance, despite an attempt by one of the challengers to invoke collateral estoppel based on Barr's earlier vacated district court judgment. Id. at 126-27.

The district court dismissed the subsequent antitrust action brought by consumers, third-party payors and consumer advocacy groups alleging that they were forced to pay higher prices for

tamoxifen as a result of the Zeneca/Barr settlement agreement. The court reasoned: "The lack of competition was not the result of any anti-competitive conduct by Zeneca or Barr, but rather the result of the existence of the '516 patent and the decision by the patent holder to enforce it." Id. at 138. In reaching this conclusion, the court did not independently assess the probable validity of the patent, even in light of the earlier district court's finding of invalidity and unenforceability, although it did note the traditional Walker Process-type exceptions for patent antitrust liability where the patent is fraudulently procured or the infringement action was a sham. Id. at 136.

The Federal Trade Commission's approach in Schering-Plough

In a decision heavily relied on by plaintiffs for its holding that exclusion payments exceeding litigation costs up to $2 million are prohibited under the Federal Trade Commission Act, the FTC also "question[ed] the utility of a rule that would give decisive weight to an after-the-fact inquiry into the merits of the patent issues in a settled case."[12] In re Schering-Plough Corp, No. 04-10688, 2003 WL 22989651 (FTC Dec. 8, 2003) ("Schering-Plough I"), set aside and vacated, Schering-Plough Corp. v. Federal Trade Comm'n, __ F.3d __, 2005 WL 528439 (11th

[12] The ruling was recently set aside and vacated by the Eleventh Circuit on other grounds (i.e., not on the issue of the propriety of post hoc evaluations of a patent's validity).

Cir. Mar. 8, 2005) ("Schering-Plough II").

The facts of that case involved two settlement agreements – one between Schering-Plough, the brand-name manufacturer of two extended-release microencapsulated potassium chloride products, K-Dur 20 and K-Dur 10, and Upsher, a generic manufacturer, and one between Schering-Plough and American Home Products ("AHP"), another generic manufacturer. Id. at *7. The Schering/Upsher agreement, entered on the eve of the parties' Hatch-Waxman patent infringement trial, called for Schering to make payments totaling $60 million to Upsher in exchange for, inter alia, Upsher's agreement not to enter the market with any generic version of K-Dur 20 for over four years. The Schering/AHP settlement, which also ended a Hatch-Waxman patent infringement trial, required Schering-Plough to make payments totaling $30 million in exchange for AHP's agreement not to market any generic version of K-Dur 20 for at least six years. Id. After rejecting Schering-Plough's argument that it had received any other consideration for its payments than Upsher's and AHP's agreements to delay marketing (both agreements included ancillary licenses), the FTC condemned the agreements as anti-competitive, but not on the basis of a post hoc review of the patents' validity.

The FTC provided a pragmatic reason for its refusal to assess validity, which had not been previously articulated by courts considering the issue:

> An after-the-fact inquiry by the Commission into the merits of the underlying litigation is not only unlikely to be particularly helpful, but also likely to be unreliable. As a general matter, tribunals decide patent issues in the context of a true adversary proceeding, and their opinions are informed by the arguments of opposing counsel. Once a case settles, however, the interests of the formerly contending parties are aligned. A generic competitor that has agreed to delay its entry no longer has an incentive to attack vigorously the validity of the patent in issue or a claim of infringement.

Schering-Plough I, 2003 WL 22989651, at *19.[13]

Although the Eleventh Circuit heavily criticized the FTC for other aspects of its decision, it had no quarrel with the FTC's rejection of a post hoc analysis of patent validity, as its own analysis took no account of the potential invalidity of the patent. Schering-Plough II, __ F.3d __, 2005 WL 528439.

This survey of the case law reveals that, with the possible exception of the Eleventh Circuit's instructions to the district court on remand in the Valley Drug case (see discussion supra), courts assessing the legality of patent settlement agreements

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[13] Plaintiffs here have raised a similar argument, suggesting that Barr's attorneys had developed a particularly strong attack on the '444 Patent that no subsequent challenger was capable of replicating. Indir. Pls.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V ("Indir. Pls.' Count V Opp'n"), at 2-4; Indir. Pls.' Mem. of Law in Opp'n to Generic Defs.' Mot. for Summ. J. and Bayer's Mot. for Partial Summ. J. on Pls.' Claims Under the Sherman Act and Corresponding State Law Claims ("Indir. Pls.' Sherman Opp'n"), at 13. Barr's patent counsel are undoubtedly fine attorneys, but it strains credulity to maintain that only one competitor's well-funded legal team could construct such a compelling case against the patent.

have not engaged in a post hoc determination of the potential validity of the underlying patent (except in cases of Walker Process or sham litigation claims) when deciding whether an agreement concerning the patent violates antitrust law. These authorities are persuasive.

Above all, making the legality of a patent settlement agreement, on pain of treble damages, contingent on a later court's assessment of the patent's validity might chill patent settlements altogether. Moreover, as explained infra, such an approach would undermine the presumption of validity of patents in all cases, as it could not logically be limited to drug patents, and would work a revolution in patent law.

In any event, although "the reasonableness of agreements under the antitrust laws are to be judged at the time the agreements are entered into," Valley Drug, 344 F.3d at 1306, a post hoc assessment of the validity of the ciprofloxacin patent it would likely do plaintiffs little good. After all, the '444 Patent has withstood multiple subsequent challenges and its validity has been affirmed by the Federal Circuit.[14] At oral argument, plaintiffs asserted that the court should give little

[14] Indeed, there is something anomalous about the notion that plaintiffs could collect treble damages for settlement of a litigation involving a patent that has been subsequently upheld by the Federal Circuit. Even the FTC's decision in Schering-Plough outlawing exclusion payments provided for prospective relief only. Schering-Plough I, 2003 WL 22989651, at *43.

weight to these subsequent failed attacks because none of them raised what plaintiffs believe to be the most forceful attack on the '444 Patent – namely, inequitable conduct. Plaintiffs argue that this defense required extensive discovery and would take a long period of time to prepare and try, and that this explains why none of the subsequent challengers raised this issue.

But this argument is not very convincing in light of the fact that one of the challenges - Carlsbad's, on the ground of obviousness – also required extensive discovery and resulted in a nine-day bench trial. It is difficult to accept the notion that Carlsbad abandoned a stronger argument because it would have presumably required a greater effort, especially since Barr had already done most of the preparatory work on the inequitable conduct issue.

Plaintiffs further argue that the '444 Patent that emerged from reexamination in the PTO after Bayer's settlement with Barr was much changed from the '444 Patent that Barr had challenged, insinuating that the allegedly strong inequitable conduct defense that Barr had developed would be weaker, or possibly even unavailable, in the hands of challengers of the reexamined '444 Patent. Indir. Pls.' Count V Opp'n, at 3. This is clearly wrong, since the defense of inequitable conduct was available for all the '444 Patent's post-reexamination challengers. See Molins PLC v. Textron, Inc., 48 F.3d 1172, 1182 (Fed. Cir. 1995)

(affirming a finding of inequitable conduct, notwithstanding that the withheld reference was later cited during reexamination and the claims were allowed to issue). Thus, the ability of the patent to withstand the subsequent challenges is persuasive, and the there is little likelihood that plaintiffs here would prevail in a post hoc attack on the patent.

In sum, it is inappropriate for an antitrust court, in determining the reasonableness of a patent settlement agreement, to conduct an after-the-fact inquiry into the validity of the underlying patent. Such an inquiry would undermine any certainty for patent litigants seeking to settle their disputes. In addition, exposing the parties to a patent settlement agreement to treble antitrust damages simply because the patent is later found to be invalid would overstep the bright-line rule adopted by the Supreme Court in Walker Process, first elaborated upon by Justice Harlan in his concurrence and relied upon by the patent bar for the past forty years. Walker Process, 382 U.S. at 179-80, 86 S.Ct. at 351-52 (1965).[15]

[15] Indirect plaintiffs have added Count V to their complaint, alleging a state law Walker-Process-type claim, namely that Bayer obtained the '444 Patent through fraud and that its suit against Barr was a sham litigation. These allegations are discussed more fully in connection with Bayer's motion to dismiss, see infra Part 3.

ii. The effect of the possible invalidity of the patent on the legality of the Agreements

Having resolved that the validity of the '444 Patent should not be independently assessed, the next question that needs to be addressed is how the possibility that the patent is invalid should affect the legality of an exclusion payment. The heart of plaintiffs' argument is that there was at least a chance that the '444 Patent was invalid and, therefore, the Agreements violated antitrust law because the patent rights they enforce derive from a potentially invalid patent. They argue that the potential invalidity of the patent translates into a potential for open competition (and, hence, lower prices), and that the possibility of realizing such open competition was unfairly foreclosed by the Agreements.

Although plaintiffs do not attempt to litigate the validity of the '444 Patent in their motion for summary judgment, or in their opposition to defendants' motions for summary judgment, they do argue that the patent's potential invalidity should be taken into account when assessing whether the anti-competitive effects of the Agreements exceed the exclusionary scope of the patent. These arguments, plaintiffs assert, do not depend on an analysis of the '444 Patent's validity. In that regard, plaintiffs advance the reasoning of the FTC in Schering-Plough, now rejected by the Eleventh Circuit, and the views of several

academics.

The starting point of the FTC's analysis whether the exclusion payments in that case were anti-competitive was to compare the amount of competition that occurred under the exclusion payment to "the amount of competition that was likely to occur had it not been for the payment . . . ." Schering-Plough I, 2003 WL 22989651, at *16. The FTC then examined and rejected Schering's defense that the restraint on trade due to the exclusion payment was ancillary to the legitimate settlement of a patent dispute, reasoning that the amount of the payment ($60 million) was too high to be "a reasonably necessary element of a settlement that is procompetitive overall." Id. at 21. The FTC also rejected as implausible Schering's separate justification for the payment, that it was in exchange for some licenses. Id. at 40. The FTC concluded that the payment was made in exchange for delayed entry, and was therefore an agreement that "unreasonably restrains commerce." Id.

Plaintiffs note that the FTC relied on the economic analysis advocated by Professor Carl Shapiro in his article Antitrust Limits to Patent Settlements, 34 Rand J. Econ. 391 (2003), see Dir. Pls.' Summ. J. App., Tab 16, in which he states that, like litigants to a patent infringement suit, consumers have an "expected" gain from the patent challenge that equals their actual gains if the patent is invalidated, discounted by the

probability of its being upheld. Dir. Pls.' Mem. at 14. The parties to the litigation, Professor Shapiro argues, should not be allowed to bargain away this assumed consumer surplus in reaching their settlement. Shapiro, 34 Rand J. of Econ. at 396 ("[A] patent settlement cannot lead to lower expected consumer surplus than would have arisen from ongoing litigation. Effectively, consumers have a 'property right' to the level of competition that would have prevailed, on average, had the two parties litigated the patent dispute to a resolution in the courts.").

This concept of a public property right in the outcome of private lawsuits does not translate well into the realities of litigation, and there is no support in the law for such a right. There is simply no legal basis for restricting the rights of patentees to choose their enforcement vehicle (i.e., settlement versus litigation). Equally important, there is no duty to use patent-derived market power in a way that imposes the lowest monopoly rents on the consumer. See, e.g., E. Bement & Sons, 186 U.S. at 91, 22 S.Ct. at 755; Studiengesellschaft Kohle, 670 F.2d at 1127. Requiring parties to a lawsuit either to litigate or negotiate a settlement in the public interest, at the risk of treble damages is, as a practical matter, tantamount to establishing a rule requiring litigants "to continue to litigate when they would prefer to settle" and "to act as unwilling

private attorneys general and to bear the various costs and risks of litigation." Nestle Co., Inc. v. Chester's Market, Inc., 756 F.2d 280, 284 (2d Cir. 1985); see also Times Mirror Magazines, Inc. v. Field & Stream Licenses Co., 103 F. Supp. 2d 711, 741 (S.D.N.Y. 2000) ("Insisting that a court review a settlement [of a trademark suit] to assure that no public confusion will result would make such agreements of little value to the parties . . . . Parties would sensibly conclude that they might better litigate the issue of confusion to conclusion rather than reach a settlement which might later be found to be unenforceable.") (quoting T & T Mfg. Co. v. A.T. Cross Co., 449 F. Supp. 813, 827 (D.R.I.), aff'd 587 F.2d 533 (1st Cir. 1978), cert. denied, 441 U.S. 908, 99 S.Ct. 2000, 60 L.Ed.2d 377 (1979)); Gen Defs. Opp. Mem. at 16 ("Plaintiffs' rule that any of these settlements can be challenged by a third party claiming 'property rights' in some litigation outcome would increase the costs of litigation and of settlement by imbuing the entire process with an additional layer of uncertainty. Litigants would fear third-party challenges to settlements based on unknowable conceptions of what 'consumer surplus' might have occurred had litigation continued."). Although plaintiffs would no doubt argue that litigation is to be preferred in these drug patent cases, as pointed out in Cipro II, there is no support for the view that Hatch-Waxman intended to thwart settlements. Cipro II, 261 F. Supp. 2d at 256.

Furthermore, even assuming some consumer surplus that the parties are bound to respect in settlement negotiations, such an interest would first have to be quantified. In seeking to calculate this consumer surplus, plaintiffs first couch their analysis in probabilistic terms, acknowledging this court's earlier admonishment that antitrust liability cannot be predicated on the possible outcome of litigation. Dir. Pls.' Mem. at 12-23; Cipro II, 261 F. Supp. 2d at 202; Schering-Plough I, 2003 WL 22989651, at *16. In particular, plaintiffs argue that every patent has a chance of being held invalid, which should inure to the public's benefit. Dir. Pls.' Mem. at 12-23 (citing Shapiro, 34 Rand J. of Econ. at 395 ("[A] patent is best viewed as a probabilistic property right. What the patent grant actually gives the patent holder is the right to sue to prevent others from infringing the patent. Nothing in the patent grant guarantees that the patent will be declared valid, or that the defendant in the patent suit will be found to have infringed.") (emphasis in original)).

To support this approach, plaintiffs resort to generalized statements about how patents fare in the courts. Dir. Pls.' Mem. at 18 ("Defendants themselves have admitted that, except in the rarest of cases, no patent stands a greater than 70% chance of being found to be valid."). This argument has some facial appeal, as it is common knowledge that many patents, once

challenged, are ultimately held invalid and/or unenforceable. See, e.g., Dir. Pls.' Summ. J. App., Tab 15 (John R. Allison and Mark A. Lemley, Empirical Evidence on the Validity of Litigated Patents, 26 AIPLA Q.J. 185, 205 (1998) (showing that nearly half of all litigated patents are found to be invalid)).

Ultimately, however, this argument proves too much. To begin with the premise, as characterized by generic defendants, that every patent is "a little bit invalid," results in undermining the presumption of validity that Congress has afforded patents. 35 U.S.C. § 282 ("A patent shall be presumed valid."); see Generic Defs.' Mem. in Opp'n to Direct Purchaser Pls.' Mot. for Partial Summ. J., at 9. Moreover, this premise could have far-reaching effects on everyday patent transactions. See Schering-Plough II, __ F.3d at __, 2005 WL 528439, at *8 ("Indeed, application of antitrust law to markets affected by the exclusionary statutes set forth in patent law cannot discount the rights of the patent holder.") (citing Simpson v. Union Oil Co., 377 U.S. 13, 14, 84 S.Ct. 1051, 12 L.Ed.2d 98 (1964)). For example, whenever a patentee and accused infringer enter a settlement (usually a license agreement), the accused infringer always either explicitly or implicitly acknowledges the patent's validity, and in many cases must pay the patentee a royalty if it wishes to continue selling the infringing goods.

Although plaintiffs contend that entry with a license is

preferable to no entry at all, unless the license is royalty-free, the royalty itself is a barrier to entry, anathema to unfettered competition and, depending on the royalty rate, may offer minimal benefit to the public. If the settlement with a payment to a generic is to be subject to antitrust liability, even though it does not exceed the scope of the patent, the next antitrust challenge to a patent settlement might well take place in the context of a license with royalty, a result that even Professor Shapiro would presumably disfavor. See, e.g., Shapiro, Antitrust Limits to Patent Settlements, 34 RAND J. of Econ. at 395 ("[A] prohibition on settling patent disputes cannot make sense: as noted earlier, virtually every patent license can be viewed as the settlement of a patent dispute, and settlements generally can provide many benefits not only to the settling parties but to consumers as well."). To open royalty-bearing patent license agreements to antitrust scrutiny simply because patents are often held invalid when tested in litigation would undermine the settled expectations of patentees and potential infringers/licensees across countless industries. See In re Tamoxifen, 277 F. Supp. 2d at 137 ("No antitrust injury can flow from the prices at which Zeneca licensed tamoxifen to Barr."); see also Studiengesellschaft Kohle, 670 F.2d at 1127.

Plaintiffs argue, as an alternative to the probabilistic method described above, that the potential invalidity of the

patent can be inferred from the parties' behavior. Plaintiffs suggest that the settlement amount is evidence of the patent's fallibility because its value exceeds the litigation costs of fending off a challenge. Mem. of Dir. Pls. in Opp'n to Defs.' Mots. for Summ. J. at 45. Plaintiffs make the sensible argument that the higher the patentee's expectation of invalidity, the more it will be willing to pay a generic challenger to concede validity and stay out of the market. Thus, the very amount of the exclusion payment is evidence of the probable invalidity of the patent. Indeed, Bayer's own documents bear this theory out: a presentation slide prepared by Bayer's chief negotiator of the Bayer/Barr settlement contains the title, "The maximum settlement amount we should consider paying increases as the risk of losing increases." Dir. Pls.' Summ. J. App., Tab 47B, at BCP-P-0001668A-004. It is worth mentioning that the presentation slide in question includes a graph plotting Bayer's perceived risk of losing against various dollar amounts and that the amount Bayer ultimately paid Barr (approximately $398 million) is at the 20-25 percent risk-of-loss mark.[16]

However, although direct plaintiffs contend that the amount of the exclusion payment in this case - $398 million -

[16] In fact, once the $398 million is converted to the then-net present value, the corresponding perceived risk of losing is even lower.

corresponds to a perceived chance of losing of about 50 percent, in absolute numbers Bayer's perceived chance of losing would appear to be much lower. How direct plaintiffs calculated this number is difficult to fathom,[17] especially since they cite Professor Hovenkamp's explanation of expected gains and losses in analyzing the anti-competitive effects of exclusion payments, who states: "[I]f the patentee has a 25% chance of losing, it is willing to pay up to 25% of the value of its monopoly to exclude its competitors without a trial." Herbert Hovenkamp et al., Anticompetitive Settlement of Intellectual Property Disputes, 87 Minn. L. Rev. 1719, 1759 (2003). Applying this model to Bayer's situation – plaintiffs submit that Bayer stood to lose more than $1.5 billion in profits if the '444 Patent was invalidated – reveals that Bayer's payment of $398 million translates to a perceived chance of losing of 26.5 percent. Of course, Bayer's payment to Barr was likely also constrained by the maximum amount Bayer expected Barr to make if it won the lawsuit, but applying a straight "expectation" economic analysis to these facts would indicate that Bayer was relatively confident of its chances of

[17] As their expert candidly admits, "[t]he formulae underlying these calculations are complex." Dir. Pls.' Summ. J. App., Tab 33 (Expert Rep. of Keith B. Leffler, Ph.D., at 34 n.85).

winning at trial.[18]

Plaintiffs' point is well-taken that the greater the chance a court would hold the patent invalid, the higher the likelihood that the patentee will seek to salvage a patent by settling with an exclusion payment. If courts do not discount the exclusionary power of the patent by the probability of the patent's being held invalid, then the patents most likely to be the subject of exclusion payments would be precisely those patents that have the most questionable validity. This concern, on its face, is quite powerful. But the answer to this concern lies in the fact that, while the strategy of paying off a generic company to drop its patent challenge would work to exclude that particular competitor from the market, it would have no effect on other challengers of

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[18] This absolute numbers "expectation" model is interesting, particularly in that it happens to line up with the graph on Bayer's presentation slide, but there is no reason to rely upon it for an analysis of the legality of Bayer's payment to Barr. Moreover, this model may be overly simplistic, in that it does not account for other factors underlying the parties' negotiations, such as the possibility that subsequent challengers might enter the market for generic Cipro. In addition, both the indirect plaintiffs and the generic defendants asserted at oral argument that such a model should not be used in assessing the legality of the payment in this case. Indirect plaintiffs argue that a better measure of Bayer's perceived chances of winning the litigation against Barr could be extrapolated from a comparison of the actual payment to Barr's anticipated profit had it won the litigation. Generic defendants, on the other hand, accept that the expectation model could be used to approximate Bayer's perceived chances of success, but assert that the legality of the payment depends not on Bayer's subjective perception of its chances, but rather only on whether the patent litigation was a sham.

the patent, whose incentive to mount a challenge would also grow commensurately with the chance that the patent would be held invalid. See, e.g., Herbert Hovenkamp, Sensible Antitrust Rules for Pharmaceutical Competition, 39 U.S.F. L. Rev. 11, 25 (2004) ("In a world in which there are numerous firms willing and able to enter the market, an exit payment to one particular infringement defendant need not have significant anticompetitive effects. If there is good reason for believing the patent invalid others will try the same thing."). Moreover, it is unlikely that the holder of a weak patent could stave off all possible challengers with exclusion payments because the economics simply would not justify it. Cf. id. at 25 n.54 (noting "ample history of litigation among large numbers of rivals being settled with a comprehensive licensing agreement," but acknowledging that those settlements "typically did not involve exit payments, but rather cross-licenses"). It could, therefore, be expected that the market would correct for any bolstering of flagrantly invalid patents by way of exclusion payments.[19] See, e.g., Andrx Pharma., Inc. v. Biovail Corp.

[19] A similar argument could be constructed for situations, unlike the one here, where infringement is the dominant issue in the underlying patent litigation. If the scope of the claims is in dispute, but arguably narrow enough that not every bioequivalent generic drug would infringe the patent, it could be expected that additional generic challengers would be spurred to design around the patent and file their own ANDA IVs based on non-infringement.

Int'l, 256 F.3d 799, 814 (D.C. Cir. 2001) ("Antitrust law looks at entry into the market as one mechanism to limit and deter exploitation of market power by those who may temporarily possess it. 'Existing firms know that if they collude or exercise market power to charge supracompetitive prices, entry by firms currently not competing in the market becomes likely, thereby increasing the pressure on them to act competitively.'") (quoting FTC v. H.J. Heinz Co., 246 F.3d 708, 717 n.13 (D.C. Cir. 2001)).

Plaintiffs counter that such a market correction would have no impact on the injury to the market in the period before a subsequent challenger successfully invalidates the patent. But that is true in the case of all patents, not just pharmaceutical patents. Unless and until the patent is shown to have been procured by fraud, or a suit for its enforcement is shown to be objectively baseless, there is no injury to the market cognizable under existing antitrust law, as long as competition is restrained only within the scope of the patent. Cf. Schering-Plough II, __ F.3d at __, 2005 WL 528439, at *8 ("By virtue of its '743 patent, Schering obtained the legal right to exclude Upsher and ESI from the market until they proved either that the '743 patent was invalid or that their products . . . did not infringe Schering's patent."). More significantly, this type of delay is entirely within the control of the would-be subsequent challengers, who alone decide when they will challenge the patent

by filing an ANDA IV.[20]

Plaintiffs further argue that the very fact that Bayer made an exclusion payment evidences the anti-competitive nature of the Agreements because a brand-name manufacturer's exclusion payments "eliminate its expected losses under litigation – and therefore eliminate consumers' expected gains under litigation . . . ." Dir Pls.' Mem. at 17. Plaintiffs again point to the FTC's decision:

> If there has been a payment from the patent holder to the generic challenger, there must have been some offsetting consideration. Absent proof of other offsetting consideration, it is logical to conclude that the quid pro quo for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise.

Schering-Plough I, 2003 WL 22989651, at *16. The problem with this argument is that, due to the disparity between the brand-name manufacturer's and generic challenger's expected profits, there might not be any date that represents a reasonable litigation compromise for early (pre-patent expiration) entry by

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[20] Barr filed its ANDA IV on the first day it was permitted to do so under 21 U.S.C. § 355(j)(5)(D)(ii). See Cipro II, 261 F. Supp. 2d at 194. There was no legal bar to other generics filing ANDA IVs that same day or any day thereafter, although pragmatic and economic considerations may have influenced their decision to wait at least until Barr's challenge had concluded before launching their own attacks on the '444 Patent. This is because if Barr were successful, the marketing approval for other generics would be withheld until Barr's 180-day exclusivity period expired.

the generic challenger. The FTC acknowledges that "[t]he anticipated profits of the patent holder in the absence of generic competition are greater than the sum of its profits and the profits of the generic entrant when the two compete." Id. Thus, for each day of early (royalty-free) entry by the generic challenger, the brand-name manufacturer will lose many times more in expected profits than the generic challenger will gain. This is, of course, the reason why brand-name manufacturers make exclusion payments rather than granting a license. There simply is no otherwise reasonable litigation compromise.

Moreover, plaintiffs' assertion that Bayer's payment to Barr is anti-competitive because, without it, Bayer and Barr would have agreed on an earlier entry date for Barr or would have otherwise fashioned a more pro-competitive agreement must also fail. This assertion ignores the fact that, if defendants were within their rights (more specifically, the patent right) in reaching the settlement they did, consumers have no right to second-guess whether some different agreement would have been more palatable. See, e.g., Verizon Comm'n Inc. v. Law Offices of Curtis V. Trinko, LLP, 540 U.S. 398, 415-16, 124 S.Ct. 872, 883, 157 L.Ed.2d 823 (2004) ("The Sherman Act . . . does not give judges carte blanche to insist that a monopolist alter its way of doing business whenever some other approach might yield greater competition."). In sum, Bayer and Barr cannot be penalized just

because plaintiffs can imagine a more pro-competitive settlement, if the agreement they did reach does not adversely affect competition beyond the scope of the '444 Patent.[21]

Finally, plaintiffs argue that Congress granted only a rebuttable presumption of validity, not a conclusive presumption, and that by making a payment, Bayer is buying that which Congress declined to grant. This argument was explicitly rejected by the Eleventh Circuit in Valley Drug:

> We cannot conclude that the exclusionary effects of the Agreements not to enter the market were necessarily greater than the exclusionary effects of the '207 patent merely because Abbott paid Geneva and Zenith in return for their respective agreements. If

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[21] Candor requires that I recognize that this conclusion is, to some extent, inconsistent with the view expressed in Cipro I regarding the motions to remand, where the opinion stated:

> A review of [plaintiffs'] allegations makes plain that plaintiffs have asserted at least one theory by which they may establish state antitrust violations without resorting to a determination of patent law. Plaintiffs' complaints allege there would have been generic competition in the market for ciprofloxacin prior to the expiration of Bayer's patent if Bayer had not reached an unreasonably anti-competitive agreement with Barr, HMR, and Rugby . . . [Plaintiffs] asserted that, as a matter of fact, Bayer would have authorized Barr to distribute ciprofloxacin by granting Barr a license, or by other means, had Barr not agreed to drop its challenge to the validity of the '444 patent in exchange for large cash payments.

Cipro I at 748.

Upon further reflection, I have concluded that patent law imposes no such restriction against cash payments by a patent holder, and, accordingly, antitrust law does not impose such a restriction.

> Abbott had a lawful right to exclude competitors, it is not obvious that competition was limited more than that lawful degree by paying potential competitors for their exit. The failure to produce the competing terazosin drug, rather than the payment of money, is the exclusionary effect, and litigation is a much more costly mechanism to achieve exclusion, both to the parties and to the public, than is settlement.

Valley Drug, 344 F.3d at 1309.

The FTC held that the Schering-Plough exclusion-payment patent settlements violated Section 5 of the Federal Trade Commission Act, Schering-Plough I, 2003 WL 22989651, at *43, but specifically exempted from antitrust scrutiny settlements involving only an early entry date. Id. at 19 ("Under the standard we adopt here, if the parties simply compromise on the entry date, standing alone, they do not need to worry about a later antitrust attack."). The difficulty with this approach is that it is not clear that consumers would benefit more from such an arrangement than from an exclusion-payment settlement like the one here. Presumably, the parties to a Hatch-Waxman patent litigation could settle on an early entry date with a license calibrated to achieve a similar financial result to the parties as an exclusion payment. In response to questions on this point at oral argument, indirect plaintiffs and generic defendants agreed that some sort of license, such as an exclusive license for a limited geographic area, "theoretically" could have been negotiated that would, as between the parties, approximate the

effect of an exclusion payment. Indir. Pls.' Resp. to the Court's Questions, at 3; Gen. Defs.' Resp. to the Court's Feb. 22, 2005 Questions, at 4. Bayer and Barr, however, focused as they were on defeating plaintiffs' theory that, absent the payment, Bayer and Barr would have agreed on an earlier entry date, were reluctant to concede the point. As Professor Hovenkamp points out,

> In a perfectly functioning market without transaction costs, a monopoly producer would be indifferent between producing everything itself and simply 'licensing' another to make part of its production. The license fee would be the monopoly markup, output would remain at the monopoly level as it would in any perfect cartel agreement, and the monopolist would earn the same profits, although part of them would be paid as license fees rather than as markup on goods that it produced. If all parties were completely certain that a patent was valid and infringed, a patentee would have precisely the same set of incentives. It would either produce all output under the patent itself, or else it would license some output to a rival, earning the monopoly profits as royalties. Assuming zero transaction costs, however, a firm in that position would have no incentive whatsoever to pay another firm to stay out of the market. It could exclude without paying anything at all.

Hovenkamp, 87 Minn. L. Rev. at 1750-51.

Assuming the soundness of Professor Hovenkamp's analysis (and it is hard to see how it can be contested), if the monopolist's profit margins are extraordinarily high, the royalty on an early-entry license could be so high that the generic company's prices would be no lower than the brand-name

manufacturer's. In this case, given Bayer's projected price drop of 95 percent a year in the future, it is reasonable to infer that Bayer's profit margin for Cipro was in excess of 95 percent.[22] In fact, plaintiffs concede that the terms of Bayer's six-month license to Barr called for an 85 percent royalty, but they complain that the license did not benefit consumers because the royalty was so high. Indir. Pls.' Sherman Opp'n, at 26. Indeed, indirect plaintiffs argue that a drug can only be considered "generic" if it is priced at least at a ten percent discount to its branded counterpart at the end-payer level, a standard that was not met by Barr's selling price under the six-month license from Barr, because the 85 percent royalty was paid at the wholesale, not retail, level. Thus, outlawing exclusion-payment settlements in favor of early-entry licenses would not necessarily result in a public benefit or satisfy plaintiffs, unless royalty rates are also constrained. Such constraints on patent holders are, of course, impermissible. See, e.g., E. Bement & Sons, 186 U.S. at 91, 22 S.Ct. at 755 ("[T]he general rule is absolute freedom in the use or sale of rights under the patent laws of the United States. . . . The fact that the

[22] Indirect plaintiffs also allege in their pleadings that Bayer maintained an exceptional profit margin for Cipro: "Bayer's 1999 United States gross sales of Cipro were approximately $1.04 billion and its net sales (or profits) were in excess of $920 million." Indir. Pls.' Second Am. Consol. Class Action Compl. ¶ 70.

conditions in the contracts [for patent licenses] keep up the monopoly or fix prices does not render them illegal."); Studiengesellschaft Kohle, 670 F.2d at 1127 ("A patentee has the right to exclude others from profiting from the patented invention. This includes the right to suppress the invention while continuing to prevent all others from using it, to license others, or to refuse to license, and to charge such royalty as the leverage of the patent monopoly permits.") (citations omitted).

And even if royalty rates were suppressed so as to preserve some consumer benefit, at some point the interests of the patent holder and the generic would diverge so that settlement would be impossible and continued litigation the only viable course. While plaintiffs may view this as a desirable outcome, as noted, the Eleventh Circuit vacated and set aside the FTC's opinion in Schering-Plough as inconsistent with the Eleventh Circuit's holding in Valley Drug that "[s]imply because a brand-name pharmaceutical company holding a patent paid its generic competitor money cannot be the sole basis for a violation of antitrust law," unless the "exclusionary effects of the agreement" exceed the "scope of the patent's protection." Schering-Plough, __ F.3d at __, 2005 WL 528439, at *17.

A significant issue before the FTC was Schering's affirmative defense that the agreements to delay entry were

ancillary to the legitimate settlement of a patent dispute. Schering-Plough I, 2003 WL 22989651, at *9, 20. Before measuring the anti-competitive impact of the agreements against the scope of the patent, the Eleventh Circuit reviewed the FTC's determination that Schering's payments to the generic companies were not bona fide royalty payments under the licenses Schering obtained from the generics, noting that "[t]he FTC concedes that its position fails if it cannot prove a direct causal link between the payments and the delay [in the generics entering the market]." Id., __ F.3d at __, 2005 WL 528439, at *10. After rejecting the FTC's determination as "not supported by law or logic," the Eleventh Circuit then characterized the aspect of the agreements dealing with the delay in generic marketing as "ancillary restraints" which are "secondary and collateral to an independent and legitimate transaction." Id., __ F.3d at __, 2005 WL 528439, at *14. Noting that such ancillary restraints "are generally permitted if they are reasonably necessary toward the contract's objective of utility and efficiency," the Eleventh Circuit found that the delay provisions were appropriately narrow, as they reached only products that were covered by Schering's patent. Id.

Plaintiffs point to the Eleventh Circuit's lengthy discussion of whether the payments were bona fide royalty payments as a disavowal of a rule that any payment from the

patent holder for a competitor's exclusion that is within the scope of the patent is exempt from antitrust scrutiny. Letter from Steve D. Shadowen dated 3/15/2005, at 2-3. Instead, plaintiffs view that discussion as expressing agreement with plaintiffs' position that such payments in exchange for delay do in fact exceed the scope of the patent. Id. A more plausible explanation for the Eleventh Circuit's in-depth treatment of the bona fide royalty question is that the discussion framed the issue of whether the delay aspects of the agreements were ancillary restraints or not. Indeed, the Eleventh Circuit's endorsement of a rule permitting exclusion payments that do not exceed the scope of the patent could hardly be clearer:

> We have said before, and we say it again, that the size of the payment, or the mere presence of a payment, should not dictate the availability of a settlement remedy. Due to the assymetries of risk and large profits at stake, even a patentee confident in the validity of its patent might pay a potential infringer a substantial sum in settlement. An exception cannot lie . . . when the issue turns on validity (Valley Drug) as opposed to infringement (the Schering agreements). The effect is the same: a generic's entry into the market is delayed. What we must focus on is the extent to which the exclusionary effects of the agreement fall within the scope of the patent's protection. Here, we find that the agreements fell well within the protections of the '743 patent, and were therefore not illegal.

Schering-Plough II, __ F.3d at __, 2005 WL 528349, at *17 (citations and internal quotation marks omitted).

Plaintiffs also argue that the Eleventh Circuit's concluding

admonition that there is a need "to evaluate the strength of the patent," Schering-Plough II, __ F.3d at __, 2005 WL 528349, at *17, bolsters plaintiffs' argument that the potential invalidity of the '444 Patent should be taken into account when measuring the exclusionary scope of the patent. Letter from Joseph Lipofsky dated 3/14/2005, at 1-2. In the context of both the opinion as a whole and the controlling precedent of Valley Drug, this admonition is more fairly read as requiring an evaluation of the scope of the patent's claims, and not a post hoc analysis of the patent's validity, an approach which, as discussed supra at Part (1)(b)(i), has not been endorsed by any court other than the Valley Drug district court on remand.

To summarize, it would be inappropriate to engage in an after-the-fact analysis of the patent's likely validity.[23] Nor is it appropriate to discount the exclusionary power of the patent by any probability that the patent would have been found invalid. Moreover, the FTC's now-vacated rule that exclusion payments beyond litigation costs are always illegal should be rejected because it ignores the justified needs of the patent holder in the face of the risks of litigation, especially in an

[23] Of course, as previously discussed, such an inquiry would hardly redound to plaintiffs' benefit, given that the '444 Patent has already been upheld by the Federal Circuit once, that three other attacks have failed and that only a speculative attack is proposed by the plaintiffs here. See supra Part 1(b)(i).

arena where it is well-known that courts are far from error-free.[24] The test for determining the validity of the so-called reverse or exclusion or exit payment and the only question remaining is whether the Agreements constrained competition beyond the scope of the patent claims. Here, the only serious argument plaintiffs have raised in that regard is possible manipulation of the 180-day exclusivity period by Barr. However, the theory was fully briefed and disposed of in the Cipro II decision and need not be decided anew here. Cipro II, 261 F. Supp. 2d at 243-47. In short, Barr's amendment of its ANDA IV to an ANDA III cleared the way for subsequent generic companies to mount challenges to the '444 Patent, an eventuality that was borne out. At least four generic companies filed ANDA IVs after Bayer and Barr entered the Agreements, so it cannot be reasonably

[24] At least two commentators have suggested that, "[f]or purposes of antitrust analysis, there are and can be no 'wrong' decisions reached by courts in patent litigation . . . [because] [t]he substantive rights granted by Congress to patent holders are those rights . . . which a federal court determines, through congressionally prescribed process, that the patent holder possesses. Because there are no 'wrong' results generated by the patent litigation process, the patent holder improperly enlarges the innovation reward granted to him by Congress when he buys 'insurance' – in the form of exclusion of a competitor – against a 'wrong' result in the patent litigation." Keith B. Leffler and Cristofer I. Leffler, Want to Pay a Competitor to Exit the Market? Settle a Patent Infringement Case, 2 ABA Economics Committee Newsletter 26 (Spring 2002). The fallacy of this argument is that it leads to the inevitable conclusion that it is always improper for a patentee to insure against an unfavorable result by paying for a competitor's exclusion. All hedging by patentees – that is, all patent settlements – are now suspect.

argued that the Agreements created a bottleneck to future generic challenges.

Plaintiffs complain that they have been doubly harmed by the Agreements: first by the exclusion of Barr from the market, and second by Bayer's passing on the cost of the settlement payment in the form of increased prices for Cipro. However, if the Agreements themselves do not exceed the exclusionary power of the '444 Patent, any increased prices resulting from the Agreements are the result of the monopoly inherent in the patent. Indeed, "an exclusion of competitors and charging of supracompetitive prices are at the core of the patentee's rights, and are legitimate rewards of the patent monopoly." Studiengesellschaft Kohle, 670 F.2d at 1128 (citing Brulotte v. Thys Co., 379 U.S. 29, 33, 85 S.Ct. 176, 179, 13 L.Ed.2d 99 (1964) (dictum); Zenith Radio Corp. v. Hazeltine Research, Inc., 395 U.S. 100, 136, 89 S.Ct. 1562, 1583, 23 L.Ed.2d 129 (1969)). Of course, market forces may impose some limits on the prices a patentee can charge. At some point, additional competitors will be spurred to either challenge the patent or design around it, or consumers will find a more affordable (although perhaps less desirable) alternative. See, e.g., Andrx v. Biovail, 256 F.3d at 814.

To conclude, in the absence of any evidence that the Agreements created a bottleneck on challenges to the '444 Patent, or that they otherwise restrained competition beyond the scope of

the claims of the '444 Patent, the Agreements have not had any anti-competitive effects on the market for ciprofloxacin beyond that which are permitted under the '444 Patent. The fact that Bayer paid what in absolute numbers is a handsome sum to Barr to settle its lawsuit does not necessarily reflect a lack of confidence in the '444 Patent, but rather the economic realities of what was at risk. There is simply no precedent for plaintiffs' argument that the parties to a settlement are required to preserve the public's interest in lower prices. Such a rule would only result in parties being less likely to reach settlements, aside from undermining well-settled principles of patent law. Finally, to even attempt to quantify the public's interest in a patent settlement between private parties would require devaluing patents across the board, a result that would contravene the presumption of validity afforded by Congress and impact the very way patent licenses are handled in countless daily transactions.

Because plaintiffs have not shown that the Agreements had anti-competitive effects beyond the scope of the '444 Patent, it is not necessary to address the second and third steps of the rule-of-reason analysis – whether defendants can establish the "pro-competitive redeeming virtues" of the Agreements, and whether plaintiffs can "show that the same pro-competitive effect could be achieved through an alternative means that is less

restrictive of competition." K.M.B. Warehouse, 61 F.3d at 127.

(2)

Consumer Antitrust Standing

As the law now stands, the validity of a patent may be challenged only by an alleged infringer as an affirmative defense or counterclaim to an infringement action brought by the patentee, or by a declaratory judgment plaintiff, who must show

> (1) an explicit threat or other action by the patentee which creates a reasonable apprehension on the part of the declaratory judgment plaintiff that it will face an infringement suit, and (2) present activity by the declaratory judgment plaintiff which could constitute infringement, or concrete steps taken by the declaratory judgment plaintiff with the intent to conduct such activity.

Teva Pharma. USA, Inc. v. Pfizer, Inc., 395 F.3d 1324, 1330 (Fed. Cir. 2005). Therefore, at present, non-infringing consumers of patented products who may feel that they are being charged supracompetitive prices by the patentee have no cause of action to invalidate the patent.

It is also apparent that Congress did not intend to change the standing requirements for actions to invalidate patents when it passed, and still more clearly when it later amended, the Hatch-Waxman Amendments in 2003. See Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066, entitled "Access to

Affordable Pharmaceuticals" ("Medicare Amendments"). Indeed, in the Medicare Amendments, which were passed on December 8, 2003, after the issues revolving around exclusion-payment and other settlements between brand-name manufacturers and generics had already surfaced, Congress provided for explicit forfeiture of the 180-day exclusivity period that would otherwise be enjoyed by the first filer of an ANDA IV if the first filer settles its suit with the brand-name manufacturer, but only if the Federal Trade Commission or the Attorney General obtains a final decision from the Federal Trade Commission or a court that the agreement between the first filer and the brand-name manufacturer has violated the antitrust law. See 21 U.S.C. 355(j)(5)(D)(i)(V) (Supp. 2004).[25] Notably, Congress made no provision for

[25] The subsection reads

> **(V) Agreement with another applicant, the listed drug application holder, or a patent owner**
>
> The first applicant [forfeits its 180-day exclusivity period if it] enters into an agreement with another applicant under this subsection for the drug, the holder of the application for the listed drug, or an owner of the patent that is the subject of the certification under paragraph (2)(A)(vii)(IV), the Federal Trade Commission or the Attorney General files a complaint, and there is a final decision of the Federal Trade Commission or the court with regard to the complaint from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the agreement has violated the antitrust laws (as defined in section 12 of Title 15, except that the term includes section

loosening the standing requirements for challenging patents or even for forfeiture of the 180-day exclusivity period where the antitrust complaint is brought by consumers.

Given that consumers are often subjected to monopoly prices for invalid patents, it is tempting to suggest that, as a policy matter, a rule should be fashioned giving consumers of drugs – and perhaps patented goods generally – the right to challenge the validity of patents. In other words, plaintiffs should be afforded the opportunity to challenge the exclusion-payment scheme at issue here - and licensing arrangements as well – by folding in a predicate challenge to the underlying patent itself. Under the proposed rule, the consumers would have to show by clear and convincing evidence – as accused infringers must – that the subject patent was invalid. This proposal would have the effect of allowing non-infringing consumers of a patented product to seek to invalidate the patent in order to allow price-reducing competitors to enter the market. The desirability of such a change is a complex issue which is not within the competence of judges. A thorough examination of the consequences of such a change would have to be made. For example, would such a change negatively impact the willingness of drug manufacturers to invest

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45 of Title 15 to the extent that that section applies to unfair methods of competition).

in research and development? Should consumers be permitted to recover punitive damages for the overcharges they have suffered? As Justice Harlan noted, patents are often set aside for any number of technical reasons. Walker Process, 382 U.S. at 179-80, 86 S.Ct. at 351-52. Perhaps permitting only declaratory relief, together with attorneys' fees, would solve the problem of unduly punishing those who in good faith sought patents that ultimately were shown to be invalid. Another possible alternative is to limit the consumer recovery to the amount of the monopolistic overcharges. These questions lead to the inevitable conclusion that such a change in public policy should be made by Congress, and not by the courts.

(3)

Bayer's Motion to Dismiss Count V of Indirect Plaintiffs' New Complaint

Recognizing that the ultimate vindication of the '444 Patent might immunize the Agreements from antitrust scrutiny under the rule of reason, indirect plaintiffs amended their complaint to add charges that would strip Bayer of its patent immunity. Indir. Pls.' Mem. of Law in Opp'n to Bayer's Mot. for Partial Summ. J. on Count V, at 1. Six months after summary judgment motions were decided in Cipro II, indirect plaintiffs moved to amend their complaint to add claims that Bayer violated state

antitrust and/or consumer protection laws by virtue of alleged inequitable conduct before the PTO in procuring the '444 Patent and alleged sham litigation in enforcing the '444 Patent against Barr. Indir. Pls.' Second Am. Consol. Class Action Compl., ¶¶ 296-308. The substance of this new count of the complaint, Count V, is that Bayer made a series of misrepresentations to the PTO in order to secure issuance of the '444 Patent, and then, with knowledge that the patent was invalid and had been fraudulently procured, asserted the patent against Barr even though no reasonable litigant in Bayer's position "at the time of its settlement with Barr" could have expected to win the litigation. Indir. Pls.' Second Am. Consol. Class Action Compl., ¶ 305. Bayer moves to dismiss Count V on two threshold grounds: that it is preempted by federal patent law and barred by the statute of limitations.

Ordinarily, antitrust claims premised on the enforcement of a fraudulently procured patent are brought by an accused infringer as a counterclaim to the original charge of infringement. See, e.g., Nobelpharma, 141 F.3d at 1067 ("[A]n antitrust claim premised on stripping a patentee of its immunity from the antitrust laws is typically raised as a counterclaim by a defendant in a patent infringement suit.") Indirect plaintiffs' claims are unusual, both because they are brought by indirect purchasers of the patented item and because they are

asserted under state law. Whatever the reasons for indirect plaintiffs bringing Walker Process and sham litigation claims under state law, those claims are preempted by federal patent law and must, therefore, be dismissed.

28 U.S.C. § 1338(a) grants federal district courts exclusive jurisdiction over "any civil action arising under any Act of Congress relating to patents . . . ." Thus, if indirect plaintiffs' state law Walker Process and sham litigation claims "arise under" patent law, they may only be heard in federal court.[26] The Supreme Court elucidated what it means for a claim to "arise under" patent law in Christianson v. Colt Indus. Operating Corp., 486 U.S. 800, 809-11, 108 S.Ct. 2166, 100 L.Ed.2d 811 (1988). Under the well-pleaded complaint rule, plaintiffs' claim must be judged solely on the face of the complaint, without reference to any anticipated defenses; unless patent law is necessary to each and every theory under the claim, § 1338(a) jurisdiction will not be invoked. Id.

Here, indirect plaintiffs' Count V rests entirely on patent law. If indirect plaintiffs cannot prove that Bayer

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[26] Although the fact that a state law cause of action may only be heard in federal court does not necessarily mean that it is preempted by federal law, see Hunter Douglas, Inc. v. Harmonic Design, Inc., 153 F.3d 1318, 1334 (Fed. Cir. 1998), overruled on other grounds by Midwest Indus., Inc. v. Karavan Trailers, Inc., 175 F.3d 1356, 1358-59 (Fed. Cir. 1999), the inquiries are closely related and in certain circumstances do overlap.

intentionally withheld or misrepresented material information to the PTO during prosecution of the '444 Patent, their Walker Process and sham litigation claims cannot survive. Specifically, "[a] finding of Walker Process fraud requires higher threshold showings of both intent and materiality than does a finding of inequitable conduct. . . . [and] must be based on independent and clear evidence of deceptive intent together with a clear showing of reliance, i.e., that the patent would not have issued but for the misrepresentation or omission." Nobelpharma, 141 F.3d at 1070-71. There is simply no theory for proving a Walker Process antitrust violation in this case that would not require a showing of misconduct before the PTO. Furthermore, the Federal Circuit has held that "whether conduct in procuring or enforcing a patent is sufficient to strip a patentee of its immunity from the antitrust laws is to be decided as a question of Federal Circuit law." Id. at 1068 (en banc in relevant part). And while sham litigation could theoretically be shown by assertion of a patent known to be valid but not infringed, such a theory is not available in this case, where Barr admitted infringement, not just as part of the post-settlement consent judgment, but in the July 25, 1996 Stipulation and Order, entered long before the Agreements were ever negotiated. See Bayer Sherman Act App., Ex. 5 (Stipulation and Order (Barr's stipulation that it infringed the '444 Patent)). Indeed, Barr never contested infringement of

the '444 Patent, even in its December 6, 1991 Paragraph IV detailed statement which triggered the Bayer/Barr patent litigation. Bayer Sherman Act App., Ex. 2.

The fact that indirect plaintiffs' Count V not only arises out of patent law, but rests entirely on patent law, leads to two conclusions. First, jurisdiction over Count V lies exclusively in federal court. 28 U.S.C. § 1338(a); Christianson, 486 U.S. at 809-11; cf. Cipro I, 166 F. Supp. 2d at 750-51 (holding that remand was appropriate where plaintiffs had "pleaded at least one theory under which their claims for relief may be resolved without determining the validity of Bayer's patent"); but see Williams v. Del Monte Fresh Produce Co., 325 F. Supp. 2d 855, 858-60 (M.D. Tenn. 2004) (remanding to state court state law claims predicated on fraudulent procurement and enforcement of a patent, where patentee admitted invalidity of patent, thus obviating the need for the state court to adjudicate the federal question). Second, federal patent law preempts any state antitrust cause of action premised on Bayer's alleged bad faith conduct before the PTO because Count V does not allege any conduct other than conduct before the PTO. In other words, the state law remedies invoked by indirect plaintiffs are directed to allegedly tortious conduct before the PTO, not tortious conduct in the marketplace. Cf. Hunter Douglas,153 F.3d at 1334; Dow Chem. Co. v. Exxon Corp., 139 F.3d 1470, 1477 (Fed. Cir. 1998).

Indirect plaintiffs' Count V allegations parallel the abuse of process counterclaim brought in Abbott Labs. v. Brennan, 952 F.2d 1346 (Fed. Cir. 1992). There, the Board of Patent Appeals and Interferences awarded priority of invention in an interference proceeding to Brennan, even though Abbott had first conceived and reduced the invention to practice because Abbott's attorney had backdated a request for extension of time and falsely averred that the request had been timely made. Id. at 1348. Abbott brought a civil action in district court seeking to set aside the award of priority to Brennan, and Brennan counterclaimed for, inter alia, the state law tort of abuse of process. The Federal Circuit reversed the judgment of abuse of process, concluding "that the federal administrative process of examining and issuing patents, including proceedings before the PTO's boards, is not subject to collateral review in terms of the common law tort of abuse of process." Id. at 1357. The court reasoned that "[a]n additional state action would be an inappropriate collateral intrusion on the regulatory procedures of the PTO, 'under the guise of a complaint sounding in tort,' . . . and is contrary to Congress' preemptive regulation in the area of patent law." Id. (quoting Gilbert v. Ben-Asher, 900 F.2d 1407, 1411 (9th Cir. 1990)).

The allegations of Count V differ from the state law claim for unfair competition that was not preempted by federal law in

Dow. There, Dow alleged that Exxon had threatened to sue actual and prospective Dow customers for patent infringement, even though Exxon allegedly had no good-faith belief that Dow infringed the patent when Exxon made the threats and had allegedly obtained the patent by inequitable conduct. Dow, 139 F.3d at 1472. The court held that the claim was not preempted because the tort claim was "not premised upon bad faith misconduct in the PTO, but rather [was] premised upon bad faith misconduct in the marketplace." Id. at 1477. The marketplace misconduct in Dow was Exxon's threats to Dow's customers, not activity that occurred before the PTO or in the context of a litigation. Id. at 1472. Indirect plaintiffs' Count V does not allege any malfeasance in the marketplace such as threats to Barr or its customers, but instead rests entirely upon actions that occurred before the PTO. Because the allegations of Count V are coextensive with patent law, they are preempted by patent law. See, e.g., Semiconductor Energy Lab. Co., Ltd. v. Samsung Elecs. Co. Ltd., 204 F.3d 1368, 1382 (Fed. Cir. 2000) (affirming dismissal of state RICO counterclaims that "occupy a field identical in scope with the inequitable conduct defense," and noting that "[a]n additional state cause of action predicated so squarely on the acts of inequitable conduct would be 'contrary to Congress' preemptive regulation in the area of patent law.'")

(quoting Abbott, 952 F.2d at 1357).[27]

The only conduct not directly referable to the PTO that indirect plaintiffs point to as an instance of marketplace "maintenance" of the '444 Patent is Bayer's compulsory listing of

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[27] Indirect plaintiffs point to a number of cases in which state law causes of action predicated on bad faith procurement of patents have been allowed to go forward. Those cases do not alter the analysis, as none of them addresses preemption of state law Walker Process or sham litigation claims. For example, In re Relafen Antitrust Litig., 221 F.R.D. 260 (D. Mass. 2004), deals with class certification issues, and makes only passing reference to one allegation that the defendants "entered the market under the banner of a patent procured by fraud." Id. at 266. The court's analysis was limited to a determination of whether the requirements of Rule 23 were met, and it did not consider the merits of the case. Id. at 265. In subsequent opinions, the Relafen court clarified that the indirect plaintiffs in that case were pursuing their Walker Process claims as assignees of the rights of several national wholesalers (i.e., direct purchasers), and their claims were therefore not barred by Illinois Brick. See In re Relafen Antitrust Litig., 346 F. Supp. 2d 349, 368 (D. Mass. 2004); In re Relafen Antitrust Litig., 2005 WL 418086, at *17, *21 (D. Mass. Feb. 22, 2005). Significantly, none of the In re Relafen opinions discusses whether state law Walker Process claims are preempted. In both Intel Corp. v. Via Techs., Inc., 2001 WL 777085, at *6 (N.D. Cal. Mar. 20, 2001) and Bristol-Myers Squibb Co. v. Ben Venue Labs., 90 F. Supp. 2d 540, 549 (D.N.J. 2000), district courts allowed state law claims to proceed where the only ground on which the parties moved to dismiss was that the state law claims were dependent on the survival of related federal antitrust claims, which were not dismissed. Similarly, in FDI, Inc. v. W.R. Grace & Co., Inc., 1980 WL 1996, *3-4 (C.D. Cal. Sept. 29, 1980), the court refused to grant summary judgment on portions of plaintiff's federal Walker Process antitrust and related unfair competition claim based on the same allegations, although preemption is not discussed in the opinion. Thus, although indirect plaintiffs have cited several cases in which state law claims based at least in part on misconduct before the PTO have been permitted to proceed, they have at least to some extent involved non-PTO conduct. In any event, none of them is binding precedent, and none of them cites any reason why such claims are not preempted by federal patent law.

the '444 Patent in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," or the "Orange Book," as required under 21 U.S.C. § 355(b)(1). Indir. Pls.' Second Am. Consol. Class Action Compl., ¶ 243; Indir. Pls.' Responses to the Court's Questions for Oral Argument, 2/28/2005. They cite In re Buspirone Patent Litig., 185 F. Supp. 2d 363, 369-73 (S.D.N.Y. 2002), in support of the proposition that such Orange Book filings can be used as a basis for a state law action. The issue before the court in Buspirone was whether the Orange Book filings were protected activity under the Noerr-Pennington doctrine. See Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961); United Mine Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965). The district court held that the filings were not protected under Noerr-Pennington, but did not say one way or the other whether Orange Book listings constitute marketplace activity subjecting patent holders to state law antitrust remedies where the underlying alleged bad-faith conduct occurred before the PTO.

Even were one to assume that the Orange Book filing of the '444 Patent would provide a basis for a state law claim, this would not advance plaintiffs' cause here. There was nothing in the act of listing the '444 Patent in the Orange Book that was itself improper, cf. In re Buspirone, 185 F. Supp. 2d at 369-73,

and the filing, according to plaintiffs, was only improper because Bayer was using it to maintain an allegedly ill-gotten patent. But this claim in turn depends first on a showing that the '444 Patent was obtained by fraud on the PTO. Plaintiffs cannot by this collateral or backdoor method avoid preemption of their state law claim.[28]

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[28] Assuming that the mere listing in the Orange Book constituted marketplace misconduct, it is highly unlikely that indirect plaintiffs would be able to establish a Walker Process claim. Initially, Walker Process fraud requires a showing that the omission or misrepresentation to the Patent Office was so material that the patent would not have issued but for the omission or misrepresentation (a level of materiality referred to as "but for" materiality); consequently, a patent must be invalid before it can be a candidate for Walker Process fraud. See, e.g., C.R. Bard, Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1365 (Fed. Cir. 1998) ("Indeed, since the inventorship issue was not grounds of invalidity, it can not satisfy the "but for" test of fraud."); Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1070 (Fed. Cir. 1998) ("Such a misrepresentation or omission must evidence a clear intent to deceive the examiner and thereby cause the PTO to grant an invalid patent.") (emphasis added). In contrast, because the patent litigation defense of inequitable conduct does not require so high a level of materiality, it is possible for a patent to be unenforceable for inequitable conduct, but still valid. See, e.g., Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1237 (Fed. Cir. 2003) (citing PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322 (Fed. Cir. 2000). Indirect plaintiffs' reliance on Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341 (Fed. Cir. 2004) for the proposition that the materiality requirement for a showing of Walker Process fraud is met by simply pointing to the PTO's issuance of a patent is a gross misreading of the law. First, Unitherm did not depart from the standard set forth in Nobelpharma for showing "but for" materiality, and concluded: "Had the PTO not relied on this fraud, the Examiner would have reached the same conclusion as did the district court and this court . . . that no valid patent could issue from [the] application." Unitherm, 375 F.3d at 1361 (emphasis added). Second, if plaintiffs' assertion were correct

Even if plaintiffs had made a sufficient showing of marketplace misconduct by Bayer in enforcing its '444 Patent to create an issue of fact, there is a serious question whether indirect plaintiffs have standing to assert a Walker Process claim. In Asahi Glass, Judge Posner, in dicta, assumed that a Walker Process claim is only available to a patentee's

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– that simple issuance of a patent is sufficient to prove "but for" materiality – then the standard for proving Walker Process fraud materiality would be lower than the showing required for inequitable conduct and would, in fact, be met in every case. Such a conclusion is directly contrary to the Federal Circuit's holding in Nobelpharma and is not supported by Unitherm.

Furthermore, indirect plaintiffs cite eight instances of improper conduct before the PTO. Some have already been rejected by Judge Brewster as failing to establish invalidity (see Bayer AG v. Carlsbad Tech., Inc., No. 01-cv-0867-B, slip op. at 6-7 (S.D. Cal. June 7, 2002)), some by the PTO during reexamination (Bayer Pat. App. Ex. 9) and others have been conceded as not rising to the level of "but for" materiality. More importantly, indirect plaintiffs did not adduce evidence of "but for" materiality for seven of these instances. The only instance for which their expert opined "but for" materiality was a claim that Bayer's statements regarding the superiority of the "compounds of the invention" to the prior art was misleading, because Bayer withheld data showing that certain of the claimed compounds were not, in fact, superior to the prior art. Lawyer advocacy or puffery is not a basis for granting or denying a patent claim. Superiority is not the issue. What is required instead is a showing of novelty and non-obviousness for a patent to issue, 35 U.S.C. §§ 102, 103, and for that the patent examiner is presumed to have relied on data, not attorney advocacy. Cf. CFMT, Inc. v. Yieldup Int'l Corp., 349 F.3d 1333, 1342 (Fed. Cir. 2003) ("During prosecution, an applicant may submit objective factual evidence to the PTO in the form of patents, technical literature, and declarations . . . . The advantages advocacy in this case does not fit any of these categories and was unaccompanied by and not asserted to be supported by any factual evidence. Therefore, a reasonable examiner would not have found it important in deciding whether to allow the application.")

competitors. Asahi Glass, 289 F. Supp. 2d at 995 ("The claim of fraud on the patent office fails for the reason just given: if patent 723 was obtained by fraud, it was a fraud aimed at competing manufacturers of drugs, not at the suppliers of those manufacturers, and so the fraud claim cannot be pressed as an antitrust claim."). This view was earlier expressed by Judge Markey, later of the Federal Circuit, sitting by designation in Oetiker v. Jurid Werke GmbH, 671 F.2d 596, 599 (D.C. Cir. 1982) ("The Supreme Court has established that one guilty of fraudulent procurement and attempted enforcement of the patent thus procured may be liable for treble damages to competitors under the antitrust laws.") (citing Walker Process, 382 U.S. 172) (emphasis added). See also In re Remeron Antitrust Litig., 335 F. Supp. 2d 522, 529 (D.N.J. 2004) ("Walker Process and its progeny involve antitrust counterclaimants who were potential or actual competitors in patent infringement suits. In this case, Plaintiffs, as direct purchasers, neither produced mirtazapine nor would have done so; moreover, Plaintiffs were not party to the initial patent infringement suits. Plaintiffs may not now claim standing to bring a Walker Process claim by donning the cloak of a Clayton Act monopolization claim.").

Finally, Bayer moves for summary judgment that Bayer's suits against Barr and the subsequent '444 Patent challengers were not sham litigation as a matter of law. To prove sham litigation, a

plaintiff must show (1) "the lawsuit must be objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits," and (2) that the litigant's "subjective motivation" for bringing the action was a sham seeking to conceal a knowing attempt to interfere with a competitor. Professional Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60-61, 113 S.Ct. 1920, 1928, 123 L.Ed.2d 611 (1993). Here, Bayer's success in its litigations against Schein, Mylan and Carlsbad forecloses any argument that its lawsuits were shams. See id., 508 U.S. at 61 n.5, 113 S.Ct. 1928 n.5 ("A winning lawsuit is by definition a reasonable effort at petitioning for redress and therefore not a sham."). Indirect plaintiffs' argument that Bayer's successes in the post-Barr litigations are immaterial, since the '444 Patent had by then undergone reexamination, is unconvincing. As discussed supra, reexamination does not cure inequitable conduct, and the defense was available to all of the generic challengers. Molins v. Textron, 48 F.3d at 1182.

In any event, as Bayer's motion to dismiss Count V is granted on the preemption ground, it is not necessary to reach the question of whether indirect plaintiffs' state law Walker Process-type claims and sham litigation claim are barred by the statute of limitations.

Conclusion

Applying a rule of reason analysis, the first element antitrust plaintiffs must prove is that the challenged agreements had an actual adverse effect on competition in the relevant market. Here, plaintiffs have failed to demonstrate anti-competitive effects in the market for ciprofloxacin because, although the Agreements undoubtedly restrained competition, they did not do so beyond the scope of the claims of the '444 Patent. The '444 Patent allows a zone of exclusion within the bounds of its claims, and that zone is undiminished by any potential invalidity of the claims. This result is compelled by the presumption of validity Congress accorded patents and the destabilizing effect on patent law that a contrary decision would work. Any readjustment of the competing interests affected by exclusion payments is a matter better addressed by Congress than the courts.

For the foregoing reasons,

- Bayer's Motion for Partial Summary Judgment on Plaintiffs' Claims Under the Sherman Act and Corresponding State Law Claims is granted;
- Generic Defendants' Motion for Summary Judgment is granted;
- Direct Purchaser Plaintiffs' Motion for Partial Summary Judgment is denied;
- Bayer's Motion to Dismiss Count V of the Indirect Purchaser Complaint Based on Threshold Grounds is granted;

- Bayer's Motion for Partial Summary Judgment on Count V of the Indirect Purchaser Class Plaintiffs' Proposed Second Amended Consolidated Class Action Complaint is dismissed as moot;

- HMR and Rugby's motion for summary judgment is dismissed as moot;

- Direct plaintiffs' amended complaints are dismissed;

- Indirect plaintiffs' second amended consolidated class action complaint is dismissed;

- Plaintiffs' motions for class certifications are denied as moot.

The Clerk of the Court is directed to close this case.

Dated: Brooklyn, New York
March 31, 2005

SO ORDERED:

/s/
David G. Trager
United States District Judge